Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)

Decision Summary

Summary of Changes
With the exception of clarifications regarding the use of embolic protection devices and the facility certification and recertification process, we have elected not to implement the changes in covered indications for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting that were outlined in the proposed decision memorandum. Therefore, coverage for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting remains as follows:

1. Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq$ 70%. Coverage is limited to procedures performed using FDA approved carotid artery stenting systems and embolic protection devices;

2. Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7);

3. Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq$80%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7).

CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible.

The five facility certification requirements are also unchanged. We modified the process for completing facility certification and recertification in the NCD Manual. This modification includes specific data submission requirements for facility recertification as well as a timeline for this process.

CAS for patients who are not at high risk for CEA remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.

This decision only changes coverage criteria in section B4 of the Medicare NCD Manual for CAS (20.7). Coverage as determined in the other sections of 20.7 will continue without modification.

The NCD language can be found in Appendix B of this decision memorandum.

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Decision Memo

TO: Administrative File: CAG 00085R3
Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

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SUBJECT: Coverage Decision Memorandum for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

DATE: April 30, 2007

I. Decision

Summary of Changes
With the exception of clarifications regarding the use of embolic protection devices and the facility certification and recertification process, we have elected not to implement the changes in covered indications for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting that were outlined in the proposed decision memorandum. Therefore, coverage for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting remains as follows:

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CAS for patients who are not at high risk for CEA remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.

This decision only changes coverage criteria in section B4 of the Medicare NCD Manual for CAS (20.7). Coverage as determined in the other sections of 20.7 will continue without modification.

The NCD language can be found in Appendix B of this decision memorandum.

II. Background

Each year about 700,000 people in the United States experience a new or recurrent stroke. About 500,000 of these are first attacks and 200,000 are recurrent attacks (Thom, 2006). The term stroke refers to a "group of cerebrovascular disorders in which part of the brain is transiently or permanently affected by ischemia or hemorrhage, or in which one or more blood vessels of the brain are primarily affected by a pathologic process, or both" (Topol, 2002). There are three main categories of strokes: cerebral infarction (greater than 80%), intracerebral hemorrhage, and subarachnoid hemorrhage. Of the cerebral infarctions, "20% to 30% are due to atherothrombosis or thromboembolism from the extracranial or intracranial vessels" (Topol, 2002).

Treatment of carotid artery stenosis is important in preventing stroke. Currently, three mechanisms are commonly used to treat carotid stenosis; medical therapy, carotid endarterectomy (CEA), and carotid artery stenting (CAS). CEA is a surgical procedure used to prevent stroke in which the surgeon removes fatty deposits or ulcerated and stenotic plaques from the carotid arteries, the two main arteries in the neck supplying blood to the brain. Although carotid artery stenosis is an important risk factor, it was estimated that "approximately 20% and 45% of strokes in the territory of symptomatic and asymptomatic carotid arteries with 70% to 99% stenosis, respectively, are unrelated to carotid stenosis" (Barnett, 2000). In these patients, optimal medical therapy would be most important since CEA does not reduce lacunar and cardio embolic strokes.

Carotid artery stenting is performed with a catheter, usually inserted through the femoral artery, and threaded up to the carotid artery beyond the area of narrowing. A distal embolic protection device or filter is usually placed first to catch emboli or debris that may dislodge during the procedure. A self-expandable or balloon-expandable, metal mesh stent is then placed to widen the stenosis and the protection device is removed.

On August 2, 2006, CMS accepted a formal request for a national coverage analysis (NCA) for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting. In the past six years, CMS has expanded coverage of PTA and CAS through three separate NCDs.

Under the current NCD, patients at high risk for CEA who have symptomatic carotid artery stenosis $\geq$ 70% are covered for procedures performed using FDA-approved CAS systems and embolic protection devices in facilities approved by CMS to perform CAS procedures. In addition, patients at high risk for CEA with symptomatic carotid artery stenosis between 50% and 70% and patients at high risk for CEA with asymptomatic carotid artery stenosis $\geq$ 80% are covered in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post approval studies (Medicare NCD Manual 20.7 B3).

Under the existing policy, CMS also required that each facility certify every two years that it meets the minimum facility standards outlined in the March 17, 2005 NCD. Those standards are summarized here. Please reference the Medicare National Coverage Determinations (NCD) Manual 20.7B4 for the complete facility standards:

- Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program.
- Advanced physiologic monitoring must be available in the interventional suite.
- Emergency management equipment and systems must be readily available in the interventional suite.
- Each institution should have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole.
- The facility or a contractor to the facility must collect and analyze data on all carotid artery stenting procedures done at that particular facility.

CMS allows initial certification that these standards are met if a letter is submitted to CMS attesting that:

1. The facility was an FDA approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER; or
2. The facility is an FDA approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST; or
3. The facility is an FDA approved site for one or more FDA post approval studies; or
4. The facility is a non-FDA approved facility that meets the minimum facility standards;

The requestor, Guidant Endovascular Solutions, which has since become part of Abbott Neurovascular Laboratories, requested the following changes to the CAS coverage policy:

- *Provide coverage of CAS for the treatment of carotid artery disease in high surgical risk patients who are symptomatic with ≥ 50% stenosis or asymptomatic ≥ 80% stenosis and determined by the treating physician to require carotid revascularization.*
- *Remove the language in the current policy stating the patient be a poor candidate for CEA 'in the opinion of a surgeon.'*

CMS used this opportunity to explore the possibility of establishing a more formal facility recertification process.

In the proposed decision released on February 1, 2007 (http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=194), CMS proposed the following changes to the current NCD:

- Restrict the current coverage for patients who are at high risk for carotid endarterectomy (CEA) and have symptomatic carotid artery stenosis ≥ 70% to patients who are less than 80 years of age;
- Expand coverage to patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80% and are less than 80 years old;
- Establish that the surgeon performing the surgical consultation that determines a patient's high risk status must be properly credentialed to perform CEA as determined by the facility.

CMS proposed the following clarifications to the current NCD:

- CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible;
- The five facility certification requirements are unchanged. We propose to modify the process for completing the certification and recertification process in the NCD Manual.

CMS proposed to maintain current coverage for CAS as follows:

- Patients at high risk for CEA who have symptomatic carotid artery stenosis between 50-70%;
- Patients who are > 80 years of age with either symptomatic stenosis ≥ 70% or asymptomatic stenosis ≥ 80% in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), the clinical trial policy (Medicare NCD Manual 310.1), or the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7B3);
- CAS for patients who are not at high risk for CEA in the opinion of a surgeon credentialed to perform carotid endarterectomy remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.

III. History of Medicare Coverage

History of Medicare Coverage for Percutaneous Transluminal Angioplasty

Over the past six years, Medicare has expanded coverage for PTA and stenting of the carotid artery. Medicare first covered PTA of the carotid artery concurrent with stent placement in accordance with the FDA-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials and later in FDA required post approval studies (Medicare NCD Manual 20.7B2, B3).

Current Medicare Coverage of Percutaneous Transluminal Angioplasty

Effective March 17, 2005, Medicare expanded coverage of PTA of the carotid artery when performed on patients at high risk for CEA who also have symptomatic carotid artery stenosis $\geq$70% only when performed in a CMS approved facility for CAS with FDA-approved carotid artery stenting systems and embolic protection devices (Medicare NCD Manual 20.7B4).

Effective November 6, 2006, Medicare established coverage for PTA and stenting of intracranial vessels for the treatment of cerebral artery stenosis $\geq$50% in patients with intracranial atherosclerotic disease when furnished in accordance with FDA-approved protocols governing Category B IDE clinical trials. All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

Reconsideration

Guidant Corporation/Abbott Vascular Solutions requested that CMS reconsider the current coverage policy for CAS. They specifically request broad coverage for high surgical risk patients meeting the FDA-approved indications for use as well as the removal of the language 'in the opinion of a surgeon' in the current NCD.

Discussion of Related NCDs

Medicare's NCD for PTA concurrent with carotid stenting can be found in NCD Manual 20.7. Medicare's NCD for PTA concurrent with carotid stenting in FDA post approval studies can also be found at NCD Manual 20.7B3.

Benefit Category

For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. PTA of the carotid artery concurrent with stenting, at a minimum, falls under the benefit category set forth in section §1861(b)(3) (inpatient hospital services), a part A benefit under §1812(a)(1) and §1861(s)(1) (physician services), a part B benefit. This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

August 2, 2006	CMS accepts Guidant Corporation/Abbott Vascular Solutions' formal NCD reconsideration request for expanded coverage of carotid artery stenting with distal embolic protection. The tracking sheet is posted and the initial 30-day public comment period begins.
September 1, 2006	Initial 30-day public comment period closes. Comments are posted on website.
February 1, 2007	Proposed decision memorandum is posted and the 30-day public comment period begins.
April 30, 2007	Final decision memorandum posted. NCD becomes effective.

V. FDA Status

Currently, five carotid stenting systems, comprised of the balloon angioplasty, stent, and embolic protection device, are approved for market by the FDA. These FDA-approved carotid stent systems are indicated for the improvement of lumen diameter in patients with occlusive carotid artery disease who are considered at high risk for adverse events from CEA and are 1) symptomatic with $\geq$ 50% stenosis; or 2) asymptomatic with $\geq$ 80% stenosis.

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendices. In general, features or clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

In this reconsideration, we considered studies and evidence that were published after the prior decision that addressed carotid artery stenting in 2005 (NCD 20.7B(4)).[1] There have been several studies reported since the prior decision. The most commonly considered health outcomes have included mortality, stroke, myocardial infarction and adverse events. As noted in the prior decision, patients enrolled in the clinical studies have been generally classified by the presence or absence of symptoms from their carotid artery stenosis. This continues to be an appropriate distinction given the differing risks of stroke, indications for treatment, and benefits of intervention. Since this is a reconsideration, we have taken the opportunity to re-examine not only what was restricted but also what was covered, the requirements of coverage, and aspects of physician training and facility certification. Following the classification of the prior decision, this National Coverage Analysis (NCA) focuses on the following main questions:

- Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with symptomatic carotid artery stenosis $\geq$ 50%?

- Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with asymptomatic carotid artery stenosis ≥ 80%?

In addition, during the review of the evidence, a striking finding about the outcomes of CAS in patients ≥ 80 years of age became apparent and indicated the need for an additional coverage question as follows:

- Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery and ≥ 80 years of age?

B. Discussion of evidence reviewed

1. Literature Search

Because this is a reconsideration, CMS focused on reported studies since the prior decision and searched PubMed from 2005 to present. General keywords included carotid artery and stenting or stent. Studies must have presented original data, examined primary health outcomes and been published in peer-reviewed English language journals. Abstracts were excluded.

2. External technology assessments and clinical reviews

Grant MD. Angioplasty and stenting of the cervical carotid artery with embolic protection of the cerebral circulation. TEC Assessments, 2007; 22(1). In press.

The Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) reevaluated PTA and carotid artery stenting with distal embolic protection. Similar to the 2005 results, the TEC concluded: "use of carotid artery angioplasty and stenting with or without embolic protection of the cerebral circulation for patients with carotid artery stenosis does not meet the TEC criteria"

(http://www.bcbs.com/betterknowledge/tec/press/actions-taken-by-the-medical-1.html).

Blue Cross and Blue Shield Association Technology Evaluation Center. Angioplasty and Stenting of the Cervical Carotid Artery with Distal Embolic Protection of the Cerebral Circulation. Assessment Program Volume 19, No. 15 February 2005.

The Blue Cross and Blue Shield Medical Advisory Panel made the following judgments about whether carotid artery angioplasty and stenting with or without distal embolic protection meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria to reduce stroke risk from symptomatic or asymptomatic carotid stenosis:

1. A single FDA approved device is currently available. Several other devices are under consideration.
2. Available evidence does not permit conclusions on outcomes of CAS with DEP for any indication considered in the assessment.
3. Available evidence is insufficient to permit conclusions as to whether CAS with DEP improves net health outcomes.
4. Whether CAS with DEP is as beneficial as either CEA or optimal medical management for high surgical risk patients cannot be determined since available evidence is insufficient to permit conclusions.
5. Whether CAS with DEP improves health outcomes has not yet been demonstrated in the investigational setting.

Based on these conclusions, the BCBS Medical Advisory Panel determined that the use of carotid artery angioplasty and stenting with or without distal embolic protection for patients with carotid artery stenosis does not meet the TEC criteria.

Bates ER, Babb JD, Casey DE, Cates CU, Duckwiler GR, Feldman TE, Gray WA, Ouriel K, Peterson ED, Rosenfield K, Rundback JH, Safian RD, Sloan MA, White CJ. ACCF/SCAI/SVMB/SIR/ASITN 2007 clinical expert consensus document on carotid stenting: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents (ACCF/SCAI/SVMB/SIR/ASITN Clinical Expert Consensus Document Committee on Carotid Stenting). J Am Coll Cardiol 2007;49:126 –70.

This clinical expert consensus document was "intended to provide a perspective on the current state of carotid artery stenting (CAS)." It reviewed similar issues to those addressed in this decision, such as clinical evidence on CEA and CAS, recommendations, high surgical risk criteria, training and credentialing. The authors reported: "Carotid artery stenting is a reasonable alternative to CEA, particularly in patients at high risk for CEA." For CEA, the group noted the American Heart Association recommendations (See following references: Goldstein, 2006 and Sacco, 2006).

Goldstein LB, Adams R, Alberts MJ, Appel LJ, Brass LM, Bushnell CD, Culebras A, DeGraba TJ, Gorelick PB, Guyton JR, Hart RG, Howard G, Kelly-Hayes M, Nixon JVI, Sacco RL. Primary prevention of ischemic stroke: a guideline from the American Heart Association/American Stroke Association Stroke Council: Cosponsored by the Atherosclerotic Peripheral Vascular Disease Interdisciplinary Working Group; Cardiovascular Nursing Council; Clinical Cardiology Council; Nutrition, Physical Activity, and Metabolism Council; and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Stroke 2006;37:15831633.

This guideline provided "an overview of the evidence on various established and potential stroke risk factors and provides recommendations for the reduction of stroke risk." Specifically for asymptomatic carotid stenosis, the authors stated:

"It is recommended that patients with asymptomatic carotid artery stenosis be screened for other treatable causes of stroke and that intensive therapy of all identified stroke risk factors be pursued (Class I, Level of Evidence C). The use of aspirin is recommended unless contraindicated because aspirin was used in all of the cited trials as an antiplatelet drug except in the surgical arm of 1 study, in which there was a higher rate of MI in those who were not given aspirin (Class I, Level of Evidence B). Prophylactic carotid endarterectomy is recommended in highly selected patients with high-grade asymptomatic carotid stenosis performed by surgeons with <3% morbidity/mortality rates (Class I, Level of Evidence A). Patient selection should be guided by an assessment of comorbid conditions and life expectancy, as well as other individual factors, and be balanced by an understanding of the overall impact of the procedure if all-cause mortality is considered as one of the end points, and it should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences. Carotid angioplasty–stenting might be a reasonable alternative to endarterectomy in asymptomatic patients at high risk for the surgical procedure (Class IIb, Level of Evidence B); however, given the reported periprocedural and overall 1-year event rates, it remains uncertain whether this group of patients should have either procedure."

Sacco RL, Adams R, Albers G, et al. Guidelines for prevention of stroke in patients with ischemic stroke or transient ischemic attack: A statement for healthcare professionals from the American Heart Association/American Stroke Association Council on Stroke: Co-Sponsored by the Council on Cardiovascular Radiology and Intervention: The American Academy of Neurology affirms the value of this guideline. Stroke 2006:37;577-617.

This guideline provided "recommendations on the prevention of ischemic stroke among survivors of ischemic stroke or transient ischemic attack." Specific recommendations were as follows:

1. "For patients with recent TIA or ischemic stroke within the last 6 months and ipsilateral severe (70% to 99%) carotid artery stenosis, CEA by a surgeon with a perioperative morbidity and mortality of <6% (Class I, Level of Evidence A) is recommended. For patients with recent TIA or ischemic stroke and ipsilateral moderate (50% to 69%) carotid stenosis, CEA is recommended, depending on patient-specific factors such as age, gender, comorbidities, and severity of initial symptoms (Class I, Level of Evidence A). When the degree of stenosis is <50%, there is no indication for CEA (Class III, Level of Evidence A) (Table 4)."

2. "When CEA is indicated for patients with TIA or stroke, surgery within 2 weeks is suggested rather than delaying surgery (Class IIa, Level of Evidence B)."

3. "Among patients with symptomatic severe stenosis (>70%) in whom the stenosis is difficult to access surgically, medical conditions are present that greatly increase the risk for surgery, or other specific circumstances exist such as radiation-induced stenosis or restenosis after CEA, CAS is not inferior to endarterectomy and may be considered (Class IIb, Level of Evidence B). CAS is reasonable when performed by operators with established periprocedural morbidity and mortality rates of 4% to 6%, similar to that observed in trials of CEA and CAS (Class IIa, Level of Evidence B)."

4. "Among patients with symptomatic carotid occlusion, EC/IC bypass surgery is not routinely recommended (Class III, Level of Evidence A)."

Cremonesi A, Setacci C, Bignamini A, et al. Carotid artery stenting. First Consensus document of the ICCS-SPREAD Joint Committee. Stroke 2006;37:2400-2409.

Cremonesi and colleagues presented an evidence-based guideline and consensus document on CAS for the Italian Consensus Carotid Stenting (ICCS)/SPREAD [Stroke Prevention and Educational Awareness Diffusion] group [a multidisciplinary association representing > 30 scientific societies and patient organizations in the field of cardiovascular disease, which, during the last 7 years, has released 4 editions of evidence-based guidelines for stroke prevention and treatment (http://www.spread.it)]. The consensus document addressed "the main issues related to methodology, definition of symptomatic and asymptomatic carotid stenosis, indication and procedures for carotid artery stenting, including the use of devices for preventing procedural embolic complications." In addition, the group addressed "credentials and competency for physician qualifications to perform vascular angioplasty and stent placement, including training, acceptable complication rates and certification."

The report states:

- "Given that current evidence is still insufficient, endarterectomy should not be systematically replaced with endovascular procedures for the elective correction of carotid stenosis." Recommendation 3: Grade A (At least 1 meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population; or systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results).

- "CAS, if performed with adequate procedural quality levels, should be used instead of endarterectomy in the presence of severe vascular or cardiac comorbidities or specific conditions." Recommendation 4: Grade B (A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+).

The group defined high risk as the following:
"Conventionally, high risk for surgery is suspected in the presence of:
Specific conditions:

- contralateral laryngeal nerve palsy;
- radiation therapy to the neck;
- previous CEA with recurrent restenosis;
- high cervical internal carotid/below the clavicle common carotid lesions;
- severe tandem lesions;
- age > 80 years;
- severe pulmonary disease.

Severe vascular and cardiac comorbidities:

- congestive heart failure (New York Heart Association class III/IV) and/or known severe left ventricular dysfunction;
- open heart surgery needed within 6 weeks;
- recent myocardial infarction (> 24 hours and < 4 weeks);
- unstable angina (Canadian Cardiovascular Society class III/IV);
- contralateral carotid occlusion.

This definition of high risk, however, is not evidence based and is not universally shared."

For physician training, the group states:
"Once the basic skill for catheter-based intervention has been achieved by the already-active interventionist, the minimum recommended training to achieve competence is as follows:

- At least 150 procedures of supra-aortic vessel engagement (during diagnostic as well as interventional procedures) within 2 years, of which at least 100 as the primary operator;
- At least 75 carotid stenting procedures, of which at least 50 as the primary operator, within a 2-year fellowship. Recommendation 10: Grade GPP (Recommended best practice based on the clinical experience of the guideline development group, without research evidence);
- The minimum requirement to maintain technical skill (competence) is the number of 50 carotid stenting procedures performed and documented by each primary operator per year. Recommendation 11: Grade GPP."

3. Internal technology assessments

Since this is a reconsideration of the 2005 policy, we focused our search on studies published or presented from the time of the prior decision. Two randomized trials, 5 case series or registry studies, 2 presentations, and 1 evidence based clinical guideline were considered.

Chaer RA, Derubertis BG, Trocciola SM, et al. Safety and efficacy of carotid angioplasty and stenting in high risk patients. American Surgeon 2006;72:694-699.

Chaer and colleagues reported the results of an observation study (vascular registry) of 545 patient who underwent CEA and 148 patients who underwent CAS. Patients were treated from 1997 to 2005 at 1 institution (outside US). All patients were considered at high risk for surgical intervention. Inclusion criteria were not specified. The main endpoint was cumulative death, stroke and MI within 30 days after the procedure, or death or ipsilateral stroke for the follow-up period. Mean age was 71 years for the CEA patients and 75 for the CAS patients. Women comprised 68% of the CEA group and 61% of the CAS group. Mean stenosis was 78% in the CEA group and 87% in the CAS group. Mean follow-up was 23 months and 18 months, respectively. The 30-day endpoint was 4% for the CEA group and 3.4% for the CAS group. All patients who underwent CAS received clopidogrel for at least 30 days. The authors concluded that "CAS is equivalent to CEA in safety and efficacy, even when performed in patients who may be at increased surgical risk" (Chaer et al., 2006).

Gray WA, Hopkins LN, Yadav S, et al. Protected carotid stenting in high-surgical-risk patients: the ARCHeR results. J Vasc Surg 2006;44:258-269.

Gray and colleagues reported the results of ARCHeR (Acculink for Revascularization of Carotids in High-Risk Patients) which was comprised of 3 case series studies of 581 patients who underwent CAS. Patients were treated from 2000 to 2003 at 48 centers (US and outside). All patients were considered at high risk for surgery. Eligibility criteria included symptomatic stenosis $\geq$ 50% or asymptomatic stenosis $\geq$ 80% by angiography. The primary endpoint was a composite of periprocedural ($\leq$ 30 days) death, stroke, and myocardial infarction (MI), plus ipsilateral stroke between days 31 and 365. Cumulative results were presented. Mean age was 70 years. Men comprised 67% of the patients. Most patients had asymptomatic stenosis (76%). The overall 30-day stroke, death, and MI rate was 8.3%, with 13.0% for symptomatic patients and 6.8% for asymptomatic patients. The authors concluded: "The ARCHeR results demonstrate that extracranial carotid artery stenting with embolic filter protection is not inferior to historical results of endarterectomy and suggest that carotid artery stenting is a safe, durable, and effective alternative in high-surgical-risk patients" (Gray et al., 2006). The results of the ARCHeR studies were presented earlier and considered in our prior decision.

Halabi M, Gruberg L, Pitchersky S, et al. Carotid artery stenting in surgical high-risk patients. Catheterization and Cardiovascular Interventions 2006;67:513-518.

Halabi and colleagues reported the results of a case series of 116 patients who underwent CAS. Patients were treated from 1998 to 2004 at 1 facility (outside US). All patients were considered at high risk for surgery. Both symptomatic ($\geq$ 60% stenosis) and asymptomatic ($\geq$ 70% stenosis) patients were included but results were not presented by subgroups. Endpoints included death and stroke during inpatient stay, at 30 days and 12 months. Mean age was 71 years. Men comprised 62%. During the inpatient stay, there were 3 death and strokes (2.6%). At 30 days, there were 3 death and strokes (2.8%). At 1 year, there were 4 death and stokes (7.8%). The inpatient events occurred in patients that did not receive distal protection (3/67). The authors concluded: "These results support the use of carotid artery angioplasty and stenting in high-risk patients with significant primary or secondary carotid artery stenosis" (Halabi et al., 2006).

Mas JL, Chatellier G, Beyssen B, et al. Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. N Engl J Med 2006;355:1660-1671.

Mas and colleagues reported the results of a randomized noninferiority trial, the Endarterectomy versus Angioplasty in Patients with Symptomatic Sever Carotid Stenosis (EVA-3S). The primary endpoint was incidence of death and stroke with 30 days of intervention. Inclusion criteria included TIA (transient ischemic attack) or nondisabling stroke with 120 days of enrollment, and stenosis 60-99% as determined by NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria. There was no enrollment restriction based on surgical risk so patients who were at low or high risk for CEA were included in the study. Exclusion criteria included disabling stroke (modified Rankin score $\geq$ 3), severe tandem lesions, and life expectancy < 2 years. The trial started in November 2000 and was conducted in 30 centers (France). By September 2005, 527 patients were randomly assigned to CEA (n=262; 257 completed, 0 failed) or CAS (n=265; 247 completed, 13 failed). Mean age was 70 years. Men comprised 75% of the patients. Most patients (72%) had stenosis $\geq$ 80%. At the planned data analysis in September 2005, the safety committee recommended stopping enrollment. The 30-day incidence of any stroke or death was 3.9% in the CEA group and 9.6% in the CAS group, with a relative risk of 2.5 (95% confidence intervals = 1.2 to 5.1). Patients who underwent CAS without distal protection had a higher incidence of stroke or death compared to patients who underwent CAS with distal protection (25% versus 7.9%; p-value=0.03). The trial was stopped early for reasons of both "safety and futility" as noted. The authors concluded that in "patients with symptomatic carotid stenosis of 60% or more, the rates of death and stroke at 1 and 6 months were lower with endarterectomy than with stenting" (Mas et al., 2006).

Several correspondences (Bonvini and Righini, Hamon and Riddell, Maree and Rosenfield) were published in response to the EVA-3S trial report. The authors mentioned that physician experience and use of distal embolic protection devices may have influenced the trial outcomes. Mas and colleagues replied with additional analyses that the 30-day risk of stroke or death did not differ significantly by physician CAS experience and that the 30-day risk of stroke or death was significantly higher in the CAS group compared to the CEA group when patients who did not receive distal embolic protection were excluded from the analysis (Mas et al., 2006).

Park B, Mavanur A, Dahn M, Menzoian J. Clinical outcomes and cost comparison of carotid artery angioplasty with stenting versus carotid endarterectomy. J Vasc Surg 2006;44:270-276.

Park and colleagues reported the results of a case series of 94 patients who underwent CEA (n=48) and CAS (n=46). Patients were treated from 2003 to 2005 at 1 institution (US). Eligibility criteria included asymptomatic stenosis $\geq$ 80% or symptomatic stenosis $\geq$ 50%, as measured by duplex ultrasound. Patient data were collected retrospectively. Endpoints included technical success, procedure related mortality, major adverse events, and costs. Mean age was 71 years. Men comprised 53% of the study population. There were no significant differences in technical success, 30-day mortality and stroke rates, and MI rate. The authors concluded: "CAS with neuroprotection was associated with clinical outcomes equivalent to those with CEA but had higher total hospital costs" (Park et al., 2006).

Safian RD, Bresnahan JF, Jaff MR, et al. Protected carotid stenting in high-risk patients with severe carotid artery stenosis. J Am Coll Cardiol 2006;47:2384-2389.

Safian and colleagues reported the results of a multicenter registry of 419 patients who underwent CAS [Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE)]. The primary endpoint was a composite of death, ipsilateral stroke, procedure related contralateral stroke, and MI. Patients were treated in 2004 at 32 participating centers. All patients were considered high risk. Eligibility criteria included symptomatic stenosis $\geq$ 50% and asymptomatic stenosis $\geq$ 70%. Mean age was 74 years. Men comprised 61% of the study population. Most patients had asymptomatic stenosis (83%). The primary endpoint occurred in 26 patients (6.2%). There were 8 deaths, 14 nonfatal strokes, and 4 MIs. The authors concluded: "For some patients with severe carotid stenosis and high-risk features for carotid endarterectomy, carotid artery stenting with distal embolic protection is a reasonable alternative for revascularization" (Safian et al., 2006).

The SPACE Collaborative Group. 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomized non-inferiority trial. Lancet 2006;368:1239-1247.

The SPACE (Stent-Protected Percutaneous Angioplasty of the Carotid vs Endarterectomy) Collaborative Group reported the results of a randomized non-inferiority trial that compared CEA to CAS in patients with severe symptomatic carotid artery stenosis. The primary endpoint was ipsilateral stroke or death of any cause up to 30 days after treatment. Eligibility criteria included neurological or ocular symptoms such as amaurosis fugaz, TIA, stroke in the previous 180 days and severe stenosis $\geq$ 70% by duplex ultrasound, which corresponds to $\geq$ 50% according to NASCET criteria. There was no enrollment restriction based on surgical risk so patients who were at low or high risk for CEA were included in the study. The use of a distal embolic protection device was optional. From 2001 to 2006, 1200 patients were randomly assigned to CAS (n=605; 599 followed up and included in the analysis) or CEA (n=595; 584 followed up and included in the analysis). Patients were treated at 35 trial centers in Germany, Austria and Switzerland. Mean age was 68 years. Men comprised 72% of the study population. In the CAS group, embolic protection devices were used in 27% (151/567) of the procedures. At 30 days post procedure, the primary endpoint occurred in 41 (6.8%) patients in the CAS group compared to 37 (6.3%) in the CEA group (absolute difference = 0.51; 90% CI = -1.89 to 2.91). The authors concluded: "SPACE failed to prove non-inferiority of carotid-artery stenting compared to carotid endarterectomy for the periprocedural complication rate. The results of this trial do not justify the widespread use in the short-term of carotid-artery stenting for treatment of carotid-artery stenoses" (SPACE Group, 2006).

Stanziale SF, Marone LK, Boules TN, et al. Carotid artery stenting in octogenarians is associated with increased adverse outcomes. J Vasc Surg 2006;43:297-304.

Stanziale and colleagues reported the results of analysis of a prospective registry of carotid stent patients "to determine if octogenarian status affects periprocedural as well as 1-year outcomes." From 1996 to 2004, the registry included 384 patients, including 260 from 10 trials, that were treated at 1 institution (US). Outcomes included periprocedural stroke, TIA, MI and death. There were 87 patients that were $\geq$ 80 years and 295 patients < 80 years. The investigators found that "All adverse outcomes were significantly higher in octogenarians compared with younger patients: 30-day stroke rate, 8.0% vs 2.7% (P = .02); 30-day stroke, myocardial infarction, or death, 9.2% vs 3.4% (P = .02)." The authors concluded: "Octogenarians undergoing carotid artery stenting are at higher risk than nonoctogenarians for periprocedural complications, including neurologic events and death. Major event-free survival at 1 year is also significantly better in nonoctogenarians. These risks should be weighed when considering carotid stenting in elderly patients" (Stanziale et al., 2006).

Post Approval Studies
Guidant Corporation. Carotid RX ACCULINK® / ACCUNET Post-Approval Trial to Uncover Unanticipated or Rare Events (CAPTURE), 2006.

Gray WA, Yadav JS, Verta P, et al. The CAPTURE registry: Results of carotid stenting with embolic protection in the post approval setting. Catheterization and Cardiovascular Interventions 2006; Published Online 12/14/2006 at: http://www3.interscience.wiley.com/cgi-bin/fulltext/113517832/HTMLSTARTW?CRETRY=1&SRETRY=0.

In December 2006, Guidant Corporation presented the results of CAPTURE to CMS. CAPTURE was a registry study that was mandated by the FDA as part of the PMA approval granted in September 2004. The purpose of CAPTURE was to collect data on carotid artery stenting in patients at high risk for surgery using the Guidant carotid artery stent (ACCULINK) and embolic protection device (ACCUNET), when used by a broad group of physicians under commercial use conditions. The primary endpoint was a composite of death, stroke and MI within 30 days post-index procedure. Eligibility criteria included indications according to the FDA labeling, specifically symptomatic stenosis $\geq$ 50% and asymptomatic stenosis $\geq$ 80%. At the time of the report, there were 3500 patients enrolled in the registry through 140 study sites. Mean age was 73 years with 24% of patients $\geq$ 80 years. Men comprised 61% of the registry population. Most patients had asymptomatic stenosis (86%). The primary endpoint of all stroke, death and MI occurred in 6.3% of the patients. The endpoint was 13.0% for symptomatic patients and 6.8% for asymptomatic patients. There were no statistically significant differences reported for physician experience levels. Patients $\geq$ 80 years of age had significantly higher rates of death, strokes and the composite events (9.4%) compared to patients < 80 years (5.3%). Many of the CAPTURE findings that were presented to CMS were subsequently published online.

Cordis Corporation. Carotid Artery Stenting with Embolic Protection in Patients at High Surgical Risk for Carotid Endarterectomy, 2006.

In March 2006, Cordis Corporation presented the interim results of CASES-PMS (Carotid Artery Stenting Education System Post-Market Study) to CMS. CASES-PMS was a registry study to assess safety and efficacy of CAS with distal protection in high surgical risk patients using the Cordis carotid stent (PRECISE) and embolic protection device (ANGIOGUARD), when performed by physicians outside the setting of a controlled trial with various levels of CAS experience. The primary endpoint was a 30 day composite of all death, all stroke and MI. Eligibility criteria included symptomatic stenosis $\geq$ 50% and asymptomatic stenosis $\geq$ 80%. At the time of the report, there were 1479 patients enrolled in the registry through 73 participating centers. Most patients (78%; 1157/1479) had asymptomatic stenoses. The primary endpoint occurred in 4.8% of enrolled patients. It was 5.9% for symptomatic patients and 4.5% for asymptomatic patients. There were no significant differences by physician experience (number of procedures performed).

Cordis Corporation. Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) 3 Year Results, 2006.

In March 2006, Cordis Corporation presented the 3 year follow-up results for the SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) trial which originally studied 334 patients. Similar to the published findings (Yadav et al., 2004), the CAS with embolic protection was not inferior to CEA. The 3 year cumulative percentage of death, stroke and MI was 26.2% for CAS patients and 30.3% for CEA patients (p=0.273). For the 3 year follow-up data, the number of patients included in the analysis for each group was not reported. The number of patients lost to follow-up was also not available.

4. MCAC

Not applicable.

5. Guidelines

Not applicable.

6. Professional Society Position Statements

The American College of Cardiology, American Society of Interventional & Therapeutic Neuroradiology, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, and the Society of Interventional Radiology published a joint consensus document as noted above (Bates et al., 2007)

7. Expert Opinion

During the public comment period following the posting of the proposed decision memorandum, CMS received substantive comments from various professional societies who are deeply involved in carotid artery stenting issues. In this section we summarize comments offered by each group.

American Academy of Neurology (AAN)
The AAN objects to CMS' proposal to cover asymptomatic patients at high risk for CEA who are less than 80 years of age with $\geq$ 80% stenosis. They contend that current data indicates a 30-day complication rate of death and stroke above the 3% level. They state that CAS is contraindicated unless the complication rate is below 3% and treated patients have a life expectancy of > 5 years. They also express concern about making decisions based on "registry" data, which "cannot determine efficacy."

The AAN supports CMS' proposal to restrict coverage for symptomatic patients at high risk for CEA with ≥ 70% stenosis to patients < 80 years of age. They contend that higher periprocedural complication rates for high surgical risk, symptomatic patients age 80 and above have been seen in recent data.

The AAN agrees with CMS' proposal to require a surgeon credentialed to perform CEA to determine if patients are at high risk for CEA and suggests that a physician with expertise in stroke be involved in the decision making process prior to submitting patients to CAS.

The AAN asserts that reimbursement for CAS should not be contingent upon placement of an embolic protection device (EPD). They note that while EPDs should be used whenever possible, on rare occasions, the benefit of CAS without an EPD outweighs the risk of the procedure. For these instances, operators should be required to document why an EPD was not used, but reimbursement should not be withheld.

The AAN agrees with CMS' intent to clarify the facility certification process, however they believe that the "omission of any mention of neurological and stroke services in the facilities requirements is a glaring error." They contend that an acute stroke plan should be required for any facility with a CAS program.

American Association of Neurological Surgery (AANS) and Congress of Neurological Surgeons (CNS)
The AANS/CNS disagrees with CMS' proposal to expand coverage to asymptomatic patients at high risk for CEA with ≥80% stenosis because available evidence does not support such an expansion of coverage.

The AANS/CNS also disagrees with CMS' proposal to restrict coverage for CAS in symptomatic patients at high risk for CEA with ≥ 70% to patients under the age of 80. They contend that despite poorer outcomes for octogenarians, this patient population can still benefit from CAS and should have this treatment option.

The AANS/CNS supports CMS' clarification requiring a surgeon credentialed to perform CEA to determine whether a patient is at high risk for CEA.

The AANS/CNS disagrees with CMS' proposed clarification requiring use of EPDs with all CAS procedures. They state that evidence supporting such a requirement for payment is lacking and contend that payment should be provided for cases in which the operator determines that placement of an EPD creates too much risk.

The AANS/CNS supports facility certification and oversight but opposes transferring this role to SCAI-CAP because the plan does not involve neurology, neurosurgery or neuroradiolgy. They assert that a neutral body or one representing all involved specialties should assume such a role.

American College of Cardiology (ACC)

The ACC supports CMS' proposal to expand coverage of CAS to asymptomatic patients at high risk for CEA with $\geq$ 80% stenosis, but opposes restricting coverage for patients age 80 and above. They assert that evidence does not conclusively explain why higher complication rates are seen in octogenarians and that restricting them from coverage may prevent them from receiving appropriate therapy.

The ACC opposes CMS' proposal to restrict coverage for symptomatic patients at high risk for CEA with $\geq$ 70% stenosis to patients < 80 years of age. They also disagree with CMS' proposal to not expand coverage for symptomatic patients at high risk for CEA with 50-69% stenosis. The ACC maintains that patients age 80 and above should not be disqualified from coverage based solely on age, and such a limit in treatment options may result in harming these patients. They further contend that coverage of high surgical risk patients with $\geq$ 50% stenosis is supported by "globally accepted supporting evidence for non-inferiority and perhaps superiority of CAS to CEA in high surgical risk patients in randomized prospective multi-center controlled trial (SAPPHIRE), as well as multiple FDA approved, industry sponsored registry trials."

The ACC opposes CMS' proposal to require a surgeon credentialed to perform CEA to determine if patients are at high risk for CEA because such a requirement is not supported in any literature and it will unnecessarily delay and/or restrict patient access to CAS.

The ACC contends that the proposed clarification requiring EPD use for all CAS procedures would "impose untenable burdens and risks to both physicians and patients if adopted." The ACC asserts that in certain cases, the use of an EPD may not be appropriate, but patients can still benefit from CAS and should receive the treatment and Medicare should provide reimbursement.

The ACC supports a transfer of CAS facility certification and oversight duties to the Society for Cardiovascular Angiography and Intervention's Carotid Accreditation Program (SCAI-CAP).

American Society of Interventional & Therapeutic Neuroradiology (ASITN)
The ASITN opposes CMS' proposal to expand coverage for asymptomatic patients at high risk for CEA under 80 years old with ≥ 80% stenosis because there is no evidence specifically demonstrating a greater benefit with less risk for this patient population in receiving CAS. CAS has been shown to have higher complication rates than the medical therapy arms of studies comparing CEA to medical therapy, and therefore this patient population should not be covered currently.

The ASITN also opposes CMS' proposal to limit coverage of symptomatic patients at high risk for CEA with ≥ 70% stenosis to patients less than 80 years of age. They contend that there is no evidence supporting this requirement and in fact, current data shows patients age 80 and above experience complication rates following CAS lower than the natural history for this patient population.

The ASITN suggests that rather than requiring a surgeon credentialed to perform CEA to make high surgical risk determinations, a specific and objective list of criteria, defining high risk criteria for CEA based on medical and anatomical factors should be established. They also suggest that a multidisciplinary group be able to make high risk for CEA determinations.

The ASITN disagrees with CMS' proposed clarification that EPDs must be used for all CAS procedures. They state that evidence supporting this requirement is insufficient and such a requirement may cause patients harm in cases when EPD use is risky but patients may still benefit from CAS. CAS without the use of an EPD should be covered when the operator documents specific reasons for failing to use the device.

The ASITN fully supports facility certification and recertification, but opposes a transfer of this responsibility to the SCAI-CAP plan because SCAI does not represent all specialties involved in CAS, specifically neurology, neurosurgery or neuroradiology. They believe that only a neutral or multidisciplinary body representing all specialties involved should be assigned this role. They also suggest that facility certification not be hinged on individual physicians' performance, but that the two be evaluated separately so as not to jeopardize a CAS program because one physician performs poorly.

American Stroke Association (ASA)
The ASA opposes CMS' proposal to expand coverage for asymptomatic patients at high risk for CEA with ≥ 80% stenosis. They state that evidence CMS used to make this proposal, from non-randomized registries and observational case studies, is insufficient to support such an expansion. They also contend that if an expansion in coverage is finalized, developing and completing a randomized trial comparing CEA, CAS and medical therapy will be much harder if not impossible.

Neurovascular Coalition: *Representing the AAN, American Association of Neurological Surgeons (AANS), ASITN, American Society of Neuroradiology (ASN),Congress of Neurological Surgeons (CNS), AANS/CNS Cerebrovascular Section*

The Neurovascular Coalition disagrees with CMS' proposal to expand coverage to asymptomatic patients at high risk for CEA with ≥ 80% who are less than 80 years old. They state "that the evidence is currently insufficient to support coverage for CAS" in this patient population. They also contend that an expansion in coverage for this patient population will impede the development and completion of clinical trials examining CEA, CAS and medical therapy.

The Coalition disagrees with CMS' proposal to limit coverage of symptomatic patients at high risk for CEA with ≥ 70% stenosis to those who are under the age of 80. They contend that while currently available evidence does show complication rates higher for patients age 80 and above, this "does not necessarily negate the potential benefit of the procedure in all patients over the age of 80."

The Coalition agrees with CMS' proposal to require that a surgeon credentialed to perform CEA determine patients' high risk status.

The Coalition opposes CMS' clarification that CAS is only covered when an EPD is used. They assert that while an EPD should be used where feasible, reimbursement should not be contingent upon use, but rather that operators should be required to document why an EPD was not used.

The Coalition opposes transferring facility certification and oversight authority to SCAI-CAP because it does not represent neurology, neurosurgery or neuroradiology. They contend that this role should only be performed by a neutral party or a body representing all specialties involved in CAS.

The Society for Cardiovascular Angiography and Interventions (SCAI)
The SCAI supports CMS' proposal to expand coverage to asymptomatic patients at high risk for CEA.

SCAI disagrees with CMS' proposed decision to not expand coverage to symptomatic patients at high risk for CEA with 50-69% stenosis outside of clinical trials and studies. They assert that currently available evidence supports an expansion of coverage for symptomatic patients at high risk for CEA with 50-69% stenosis who are less than 80 years old.

The SCAI opposes CMS' clarification requiring a surgeon credentialed to perform CEA to determine whether patients meet high risk criteria for CEA. They contend that such a requirement is not supported by current literature, will increase cost and workload, will create a conflict of interest and may compromise patient care.

The SCAI opposes the proposed clarification providing coverage only for CAS when an EPD is used. They state that CMS does not provide a rational for this requirement in the proposed decision memorandum. They contend that such a requirement will cause operators to force an EPD where its use is too risky or abort a procedure where the benefit of CAS is greater than the risk of not using an EPD, neither of which is in the best interest of the patient. They propose that CMS remove this proposed clarification and replace it with the original language.

The SCAI believes that assigning SCAI-CAP the facility certification and oversight role "would improve patient care by setting high standards for the training, equipping and monitoring of outcomes" at facilities that perform CAS.

Society of Interventional Radiology (SIR)
SIR supports CMS' proposal to expand coverage for asymptomatic patients at high risk for CEA with $\geq$ 80% stenosis as long as there is a net patient benefit. They state that CAS in these patients should only be covered if the outcomes can be documented as $\leq$ 3% stroke and death.

SIR supports continued study of CAS in patients age 80 and above in clinical trials and studies.

SIR disagrees with CMS' clarification requiring a surgeon credentialed to perform CEA to determine whether patients are at high risk for CEA. Rather, they suggest establishing clear, specific and unambiguous high risk criteria. If such criteria is not established or a patient's high risk status is unclear, then a surgeon should make the determination.

SIR opposes CMS' proposed clarification that an EPD must be used for CAS procedures to be covered. They assert that such a requirement may cause physicians to inappropriately force placement of an EPD or deny beneficial treatment to patients. They also contend that available evidence regarding the benefit of EPD and/or danger of not using EPD is inconclusive and thus does not support this requirement.

SIR supports CAS facility accreditation, but has concerns about SCAI-CAP. The SCAI proposal states that SIR is a collaborator on their proposal, but SIR states that they are not. They also believe that other groups listed as collaborators, like SVS, are not. SIR contends that an accreditation program must be performed by an independent or multidisciplinary entity. SIR also disagrees with the benchmarks set in SCAI-CAP and believes that a mechanism for distinguishing facility outcomes from individual physician outcomes must be established in an accreditation plan.

Society of Thoracic Surgeons (STS)
The STS opposes CMS' proposed expansion of coverage to asymptomatic patients with "physiologic" high risk comorbidities. They contend that this expansion in coverage will inhibit enrollment in and completion of important clinical trials like CREST.

The STS supports CMS' proposed decision to continue to cover symptomatic patients at high risk for CEA with 50-70% stenosis only in Category B IDE trials and FDA-approved post approval studies because sufficient evidence is not available to support an expansion of coverage for this patient population.

The STS supports CMS' proposal to restrict coverage for patients age 80 and above. They contend that current data suggests very high stroke and death rates following CAS in this patient population.

STS supports the proposed clarification requiring a surgeon credentialed to perform CEA to determine whether a patient is at high surgical risk. They state that this requirement will protect patients from liberal interpretations of high surgical risk criteria, and surgeons have proven their abilities to properly identify high surgical risk patients.

Society for Vascular Surgery (SVS)
SVS does not support CMS' proposed expansion of coverage for asymptomatic patients with "physiologic" high risk comorbidities. They contend that the only asymptomatic patient population in which CAS should be covered routinely includes patients with anatomic high surgical risk factors. SVS also states that an expansion of coverage to asymptomatic patients based on insufficient data will prevent recruitment for and completion of important randomized controlled trials (RCTs) like CREST and ACT 1.

SVS agrees with CMS' proposal to not expand coverage to symptomatic patients at high risk for CEA with 50-70% stenosis because such an expansion is not justifiable without compelling RCT data.

SVS supports restricting coverage to exclude patients age 80 and above as this "is the only responsible choice based on the available data."

SVS strongly supports the proposed clarification requiring a surgeon credentialed to perform CEA to determine whether patients are at high risk for CEA. They state that the "CEA surgeon will provide clinical balance for thousands of enthusiastic CAS providers, some with little or no experience caring for carotid disease patients, many of whom are likely to forge extremely liberal interpretations of high surgical risk."

SVS disagrees with CMS' proposed clarification providing coverage only for CAS when an EPD is used. Rather they state that coverage should be provided when the operator documents that the risk of use exceeds potential benefits or the operator documents reasonable attempts to deploy the EPD and cites why it is not possible.

SVS supports facility certification, but does not support exclusive delegation of this responsibility to SCAI-CAP. They assert that their level of involvement as described by SCAI in the SCAI-CAP proposal was overstated and they have had very limited discussions with SCAI regarding SCAI-CAP. SVS supports participating in a specialty-neutral initiative, however, they believe that CMS must discontinue its facility certification and recertification processes in order for an "intersocial effort" to succeed.

8. Public Comments

Following the release of the proposed decision memorandum (PDM) for PTA of the carotid arteries concurrent with stenting, CMS received 185 comments. The majority of these comments did not focus on the proposed changes in coverage, but rather on proposed clarifications included in the proposed decision. A large number of citations are referenced by the commenters and a complete list is available in Appendix C of this document.

Due to the extensive nature of the comments and our resulting modifications of the proposed policy based on these comments and new medical evidence, we are summarizing the comments in this section and will discuss our response to them in the Analysis Section.

Comments with Evidence

Coverage of Asymptomatic Patients at High Risk for CEA

ACSRS, 2005; ACAS, 1995; ACST, 2004

One commenter cites these studies to support CMS' proposed expansion of coverage to asymptomatic patients at high risk for CEA with ≥ 80% stenosis under the age of 80. This commenter contends that these studies show that high degrees of stenosis do not generally produce a higher risk of stroke. These patients should therefore not immediately be considered at high risk for stroke, and may benefit from CAS.

Two (2) commenters cite these studies to contend that asymptomatic patients with ≥ 80% stenosis should not be covered.

Chaer et al., 2006; Halabi et al., 2006; Verzini et al.; Stanziale et al., 2006; CaRESS, 2005; Hofmann et al., 2006; CREST, 2004

One commenter notes that these studies achieved or nearly acheived ≤ 3% perioperative stroke and death rates for asymptomatic patients at high risk for CEA with ≥ 80% stenosis who received CAS. This commenter supports CMS' proposal to cover this patient population, when under the age of 80, but recommends limiting coverage only to those procedures that meet the 3% threshold for stroke and death rate outcomes.

CAPTURE, 2006; Safian et al., 2006; CASES; SAPPHIRE

Two (2) commenters cite results from these studies, which showed 30-day complication rates following CAS to be > 3%, to oppose CMS' proposal to expand coverage for asymptomatic patients at high risk for CEA with ≥ 80% stenosis who are under 80 years old.

Halm et al., 2005; Kragsterman et al., 2006

One commenter cites these articles to oppose CMS' proposal to cover asymptomatic patients at high risk for CEA with ≥ 80% stenosis These studies show peri-procedureal stroke/death rates < 3% for these patients when treated with CEA, which is less than when treated with CAS. This commenter contends that these patients should only be covered in Category B IDE trials or FDA-approved post approval studies. This commenter also cites these studies to oppose coverage of asymptomatic patients with physiologic high-risk comorbidities.

SAPPHIRE, 2004; ARCHeR, 2006; CAPTURE, 2006; BEACH, 2006; SPACE, 2006; EVA-3S, 2006
One commenter asserts that outcomes from these studies do not provide evidence to show that CAS can be consistently performed with periprocedureal complication rates that provide a net benefit. This commenter contends that coverage should not be expanded to asymptomatic patients until evidence is available that demonstrates a net benefit for patients who undergo CAS.

Coverage of Symptomatic Patients at High Risk for CEA with 50-69% Stenosis
EVA-3S, 2006; SPACE, 2006
Seven (7) commenters cite these studies to refute CMS' rationale for not expanding coverage to symptomatic patients at high risk for CEA with 50-69% stenosis. They state that CMS' use of data from the EVA-3S and SPACE studies to maintain limited coverage for this population is inappropriate because both studies examined symptomatic, normal risk patients, rather than high risk patients, which comprise the patient population under consideration for coverage in this analysis. Because patients in these studies were at normal risk for CEA, outcomes from these studies are not applicable to this analysis. These commenters also maintain that both studies had critical flaws. EVA-3S exhibited flaws in design and conduct which bring into question the outcomes showing CAS to have significantly worse stroke and death rates than CEA. SPACE reported similar outcomes for both CEA and CAS, however the study was ended early and failed to enroll its targeted number of participants. One commenter asserts that the authors' conclusion that SPACE failed to prove non-inferiority of CAS to CEA should be changed to "the trial failed to enroll enough patients to prove non-inferiority."

Naylor AR, 2006; Furlan AJ, 2006
One commenter cites these articles to identify additional problems with SPACE and EVA-3S.

NASCET, 1991; ECST, 1998; Mayberg et al., 1991
One commenter cites these articles to stress that level 1 evidence supports coverage of symptomatic patients at high risk for CEA with $\geq$ 50% stenosis when carotid revascularization is compared to best medical therapy.

Biller et al., 1998
One commenter cites this study to contend that this patient population experiences benefit from CAS.

SAPPHIRE, 2002; Safian et al., 2006; BEACH, 2006; CAPTURE, 2006; ARCHeR, 2006
Commenters contend that these studies show CAS to be non-inferior to CEA and should therefore be covered for symptomatic patients at high risk for CEA with 50-70% stenosis.

Commenters also cite data from some of these studies on file with the manufacturing companies to support an expansion of coverage and their contention that CAS is at least non-inferior if not superior to CEA. This data has not yet been published or presented publicly.

ACSRS, 2005
Commenters note that results from this study, in which asymptomatic patients with > 80% carotid stenosis and comorbidities had a risk of stroke > 6%, suggest that symptomatic patients at high risk for CEA have an even higher risk of stroke, and therefore should be covered.

NASCET; ARCHeR
One commenter states that a comparison of the natural history risk of stroke in NASCET to risk of stroke, death, or MI (SDMI) at 30-days following CAS in ARCHeR for symptomatic patients with 50-70% stenosis supports CMS' proposal to cover symptomatic patients at high risk for CEA with 50-70% stenosis only in Category B IDE clinical trials and FDA approved post approval studies.

CAPTURE; EVA-3S
One commenter supports CMS' proposed restriction of coverage for symptomatic patients at high risk for CEA with 50-70% stenosis to Category B IDE trials or FDA-approved post approval studies due to poor reported outcomes for this patient population.

ARCHeR
Two (2) commenters assert that results from this study do not support coverage of symptomatic patients at high risk for CEA with 50-69% stenosis and therefore support the proposed decision.

Coverage of Octogenarians
Ahmadi et al., 2002; Setacci et al., 2006
Two (2) commenters cite these articles to challenge CMS' proposed limitation of coverage for octogenarians. These articles suggest that CAS may be safe for octogenarians, and the commenters contend that this decision is best made by physicians.

In the Opinion of a Surgeon
EVA-3S, 2006; SPACE, 2006

Three (3) commenters reference these studies to refute CMS' proposed requirement that a surgeon credentialed to perform CEA must determine patients to be at high risk for CEA. The commenters note the flaws in each study and the dissimilar study population to assert that supporting this requirement with data from EVA-3S and SPACE is inappropriate.

SAPPHIRE, 2002; Safian et al., 2006; BEACH, 2006; CAPTURE, 2006; ARCHeR, 2006
These studies are also cited to refute CMS' proposed clarification stating that the high risk for CEA determination must be made by a surgeon credentialed to perform CEA. Several commenters state that this requirement was not a part of any of these studies and therefore is not supported by literature.

Rothwell et al., 1996
A commenter cites this article to challenge CMS' clarification that a surgeon credentialed to perform CEA must determine whether patients meet high risk criteria for CEA. Specifically, this commenter raises concerns discussed in this article regarding self-reporting of data by surgeon authors and variability of outcomes.

Kragsterman et al., 2006; Westvik et al., 2006; Matsen et al., 2006
Two (2) commenters reference these articles to support CMS' proposed clarification that surgeons credentialed to perform CEA must determine whether patients are at high risk for CEA. These studies show that surgeons have become very competent at identifying high risk patients and referring patients to appropriate treatments.

Use of Embolic Protection Devices
EVA-3S, 2006; SPACE, 2006
Four (4) commenters cite these studies in refuting CMS' specification that all CAS procedures must be performed with embolic protection devices in order to be eligible for Medicare coverage. They contend that applying outcomes from these studies in making this determination is inappropriate due to the study flaws discussed above.

ARCHeR
One commenter cites this study, in which the stroke rate was lower for CAS procedures performed without EPDs as opposed to with EPDs, to stress the need for coverage of CAS when the placement of an EPD is not possible.

Cao et al., 2006
Two (2) commenters cite this study to stress the danger of requiring the use of embolic protection devices (EPDs) for all CAS procedures, stating that in some situations, forcing the placement of an EPD may cause more harm to the patient than performing CAS without an EPD. Therefore, the use of EPD should not be required for Medicare reimbursement in cases where placement may harm the patient.

Kastrup et al., 2006; Theiss et al., 2004; SPACE, 2006
Two (2) commenters cite these studies to demonstrate that available evidence does not necessarily show CAS with EPD to have statistically better outcomes than CAS without EPD.

Comments without Evidence

General Comments
Seven (7) commenters express general disagreement with the proposed decision while four (4) express general support of the proposal. Two (2) commenters state that the current policy should be maintained, and two (2) other commenters specify that the policy should be maintained until new level 1 evidence is available from CREST and ACT I.

CMS agress that more data are necessary to expand coverage to asymptomatic patients at high risk for CEA with $\geq$ 80% stenosis. Therefore, the final decision allows for coverage of these patients only in Category B IDE clinical trials, in FDA-approved post approval studies, or under the clinical trials policy.

One commenter requests a general expansion of coverage for CAS. Another commenter notes the importance of CAS as an alternate treatment for stroke prevention and one commenter states that CAS is the revascularization treatment of choice for physicians and patients.

CMS agrees that CAS is an important treatment option, and believes that coverage as specified in this NCD is reasonable and necessary and appropriate based on currently available evidence.

Two (2) commenters assert that an expansion of coverage will prevent ongoing clinical trials from being completed and future studies from being conducted. One commenter states that the proposed decision is not in the best interest of patients and was developed to save CMS money, not lives. One commenter warns about expanding coverage because it could lead to similar problems encountered with coronary stents. Another commenter contends that the proposed expansion of coverage is the result of CMS bowing to industry and is not in the best interest of Medicare beneficiaries and taxpayers.

CMS makes coverage decisions based on the available clinical evidence. CMS does not consider cost in making decisions, nor does it formulate NCDs to "bow" to industry pressure. Upon further evidence analysis, we have determined that the expansion of coverage for asymptomatic patients at high risk for CEA outside of clinical trials was premature and more evidence is needed to support such an expansion of coverage. We believe that the final decision will continue to make this important technology available while protecting the safety of patient populations in whom outcomes are still inconclusive and encourage further study on this patient population.

Two (2) commenters suggest that CMS specifically state in the final decision how the percentage of stenosis must be determined. One commenter states that the percentage of stenosis should be determined by cerebral angiogram or carotid duplex from ICAVL accredited labs while another commenter asserts that the use of various technologies to determine the percentage of stenosis should be acceptable for coverage.

To become approved by CMS to perform CAS, facilities must attest to meeting the minimum facility standards, one of which involves having the appropriate equipment to support a comprehensive CAS program. The specifics of these programs are expected to be determined by each facility.

Coverage of Asymptomatic Patients at High Risk for CEA

Twenty nine (29) commenters support the proposed expansion of coverage to patients who are at high surgical risk for CEA with asymptomatic stenosis $\geq$ 80% stenosis. One commenter supports this expansion of coverage as long as complication rates are $\leq$ 3%. One commenter notes that asymptomatic high surgical risk patients who have favorable anatomy for CAS are excellent candidates for CAS and should be treated.

CMS has decided to reverse the proposed decision to cover this patient population outside of clinical trials. Coverage for these patients will continue as in the previous CAS NCD. After consideration of public comments and further evidence review, we have determined that available evidence is not sufficient to conclude that coverage of patients at high risk for CEA with asymptomatic stenosis $\geq$ 80% outside of clinical trials is reasonable and necessary.

Five (5) commenters assert that coverage should not be expanded to include asymptomatic patients at high risk for CEA with $\geq$ 80% stenosis. Five (5) commenters contend that there is no evidence to support expanding coverage to these patients, and one commenter states that more evidence is needed on asymptomatic patients. Four (4) commenters argue that studies have shown complication rates for asymptomatic patients with $\geq$ 80% stenosis that exceed 3% and expanding coverage for this population will not prevent but rather lead to more stroke and death in this population. Another commenter claims that the proposed expansion of coverage is not in the best interest of beneficiaries. One commenter states that asymptomatic patients should only be covered in clinical trials and studies. Another commenter asserts that expanding coverage to this population will prevent more studies from being developed, funded and completed due to a lack of participants.

Upon further review, CMS agrees that available evidence is insufficient and has reversed the proposal to expand coverage to this patient population.

Coverage of Symptomatic Patients at High Risk for CEA with 50-69% Stenosis

Fifteen (15) commenters disagree with the proposed decision to maintain current coverage for symptomatic patients at high risk for CEA with 50-60% stenosis, which would continue to cover this patient population in clinical trials and studies. They assert that symptomatic patients with $\geq$ 50% stenosis should be covered outside of clinical trials and studies. One commenter states that symptomatic patients with $\geq$ 60% stenosis should be covered. Two (2) commenters support the proposed decision to cover these patients in Category B IDE trials and FDA-approved post approval studies. One commenter states that coverage for this patient population should not be expanded until more evidence is available.

As discussed in the analysis section of this decision memorandum, the available evidence is not sufficient to extend coverage to this patient population. Symptomatic patients at high risk for CEA with 50-69% stenosis will continue to be eligible for Medicare reimbursement in Category B IDE clinical trials and FDA-approved post approval studies.

Coverage of Octogenarians

Twenty (20) commenters disagree with the proposed limitation of coverage for patients $\geq$ 80 years of age. Eight (8) commenters assert that octogenarians should be covered because they have no alternate effective treatment to prevent stroke. Three (3) commenters state that CEA does not include this limitation and, therefore, CAS should not be subject to it. One commenter contends that surgical data shows that patients over the age of 80 have the most to gain from CAS and should therefore be covered. One commenter asserts that CEA is not proven to be superior to CAS so octogenarians should have access to CAS as well as CEA. One commenter suggests covering octogenarians in separate registries. Four (4) commenters assert that age 80 and older should be considered a high surgical risk criteria, thereby making coverage of CAS for octogenarians necessary. One commenter states that the use of CAS should be based on risk scores that incorporate age and other factors in determining appropriateness of CAS in specific patients. Eight (8) commenters contend that treatment for carotid artery disease must be determined by physicians and patients, not dictated by the federal government. Five (5) commenters assert that this proposed limitation of coverage discriminates against the elderly.

CMS agrees with many of these commenters and will not restrict coverage by age. The final decision maintains coverage for octogenarians outside of Category B IDE clinical trials and FDA-post approval studies for those who are at high risk for CEA and have symptomatic stenosis $\geq$ 70%.

Four (4) commenters state that patients who are ≥ 80 years old should not be covered. Four (4) commenters agree with covering these patients only in clinical trials and studies. Two (2) commenters note that more data is needed to better examine CAS in octogenarians. Two (2) commenters support the proposed restriction because evidence shows higher periprocedural complication rates for symptomatic patients age 80 and above after undergoing CAS, and two (2) commenters assert that available evidence does not support coverage of CAS for octogenarians.

CMS has decided to maintain coverage for octogenarians at high risk for CEA with symptomatic stenosis ≥ 70%. CMS looks forward to reviewing additional data gathered on patients ≥ 80 years of age in current and future clinical trials.

In the Opinion of a Surgeon

Fifty five (55) commenters state that the clarification in the proposed decision memorandum stating that a surgeon credentialed to perform CEA must determine if a patient is at high risk for CEA is an unfair and unethical requirement. Fifty two (52) commenters contend that CMS should not require a surgical consultation to determine a patient's risk for CEA. Thirty one (31) commenters assert that such a requirement will compromise patient care and twenty two (22) commenters state that a surgical consultation is impractical, unnecessary, burdensome, and expensive. Twenty four (24) commenters refute this requirement since cardiologists are trained to determine patients' high risk status while surgeons are not and rarely will consider a patient to be at high risk for CEA. Ten (10) commenters contend that only the treating physician should determine whether a patient is at high risk for CEA.

Eleven (11) commenters support requiring a surgeon to determine patients' high surgical risk status. Six (6) commenters assert that such a consultation is necessary to prevent overuse of CAS in non-high surgical risk patients, and to ensure patient safety and quality of care. Five (5) commenters support requiring a surgical consultation because CEA is the standard treatment for carotid artery disease and therefore surgeons have more experience with carotid disease than other physicians. One commenter states that no evidence supports CAS as equivalent to CEA therefore the surgical consultation is appropriate. One commenter suggests that the surgical consultation be optional.

Five (5) commenters state that CMS does not have the authority to make this requirement and should not take over decision making from physicians and patients. Four (4) commenters contend that this requirement demonstrates that CMS favors surgeons. Two (2) commenters assert that surgeons want CAS to fail and therefore will not appropriately classify high surgical risk patients. One commenter states that many surgeons are unethical and do not keep up with scientific literature so requiring a surgeon to make the high risk determination is inappropriate. Another commenter states that this requirement "seems like a calculated political move and not one based on scientific merit and certainly not on current standards in other specialties." One commenter contends that such a requirement will limit medical advances. One commenter asserts that CMS misinterpreted evidence to make this decision. Finally, several commenters supplement their comments with various analogies to express their disagreement with requiring a surgical consultation. Five (5) commenters compare this requirement to allowing the "fox to guard the chicken coop." Two (2) commenters liken this requirement to asking "your local barber if you need a haircut." One commenter states that requiring a surgeon to determine a patient's high surgical risk status is "like taking the cow to the butcher…what else is the butcher going to do with a cow but slaughter it…"

CMS has determined with this final decision that requiring a surgeon credentialed to perform CEA to determine whether patients are at high risk for surgery was overly restrictive. This language has been removed from the final decision but we would like to stress the importance of ensuring appropriate patient selection. As evident from the comments discussed above, this issue has created a serious "turf" war between various physicians who treat carotid artery disease. Regardless of physicians' personal feelings about their colleagues, treatment decisions still must be made in the best interest of the patient. CMS encourages physicians of different specialties to work together to determine the best course of treatment for patients with carotid artery disease. Beneficiaries will receive optimal care only when all treatment options are evaluated carefully.

High Risk for CEA

Thirteen (13) commenters contend that high surgical risk criteria should be based on criteria used in CAS studies and trials. Seven (7) commenters state that patients' surgical risk determination should be based on objective and specific criteria. Three (3) commenters suggest that the high surgical risk determination be made through a team approach rather than by an individual physician, and two (2) commenters suggest that an independent third party make the high surgical risk determination. One commenter contends that physicians with stroke expertise should be incorporated in making the surgical risk determination. Two (2) commenters assert that high risk criteria for CEA be separated by anatomic and medical factors. One commenter states that CMS must consider that high risk for CEA does not mean high risk for stroke.

One commenter contends that only patients at high risk for CEA should receive CAS, while another commenter states that non-high surgical risk patients should be covered as well. One commenter asserts that all patients at high risk for CEA under the age of 80 should be covered by Medicare.

CMS continues to reference high risk for CEA guidelines and criteria cited in CAS clinical trials as stated in the NCD language and we have clarified specific high risk criteria for CEA in the facility recertification information section of the NCD. We have also provided, in the analysis section of this document, the American College of Cardiology Foundation Task Force consensus document which provides useful information on high risk criteria to assist physicians and facilities in selecting appropriate patients for CAS (Table 7 reproduced from Bates et al., 2007).

Use of Embolic Protection Devices (EPDs)

In the proposed decision, CMS also clarifies that the use of an EPD with all CAS procedures is required for Medicare coverage. Ten (10) commenters state that CAS procedures should be covered for the few cases when EPD use is attempted but fails or is not possible, while three (3) commenters support this requirement. Five (5) commenters contend that no evidence demonstrates an increase in safety with the use of EPDs. Six (6) commenters assert that such a requirement for payment will encourage risky behavior where physicians may inappropriately force EPDs through vessels. One commenter suggests that CAS procedures without the use of EPDs receive reduced reimbursement and three (3) commenters suggest that physicians must document why an EPD was not used. Finally, one commenter contends that such a requirement demonstrates CMS favoritism toward industry.

CMS believes that these concerns are specific to reimbursement policy, not coverage policy, and a discussion of reimbursement is not appropriate for this analysis.

Facility Certification and Oversight

Three (3) commenters state that all patients at high risk for CEA should be covered by Medicare as long as all data is submitted to CMS via a registry. One commenter states that the recertification process adds more complications to patient access to CAS. One commenter asserts that acute stroke plans must be included in all CAS programs.

The recertification process discussed in this decision memo is an explanation of a requirement in the previous NCD. Facility certification and recertification is not new to this policy, nor to CMS coverage issues, and is essential to ensure procedures are performed as CMS has determined them to be reasonable and necessary, in compliance with the NCD. Data submission, an important part of this certification and recertification process, is not required to be submitted via a national registry.

Facilities may experience advantages through participation in a national registry. In particular, CMS approved registries are required to collect important data on CAS and are encouraged to collect data on CEA. They are expected to allow facilities to compare performance with other hospitals in the nation and also between physicians within a facility. CMS believes information derived from these registries is important to facilities and physicians in maintaining and improving high quality CAS programs and providing the best possible care for patients.

Three (3) commenters support the proposed changes in the data submission requirement, which they interpret to require all data to be submitted to a national registry instead of CMS. They state that proposed changes are favorable because enrollment in FDA-approved post market approval studies is unnecessary.

It appears that these commenters have misinterpreted the proposed decision memo because CMS has not proposed to require data submission to national CAS registries, nor has CMS proposed to make changes to the policy to eliminate enrollment in FDA-approved post market approval studies. These are not changes that were discussed or even suggested in the proposed decision memo and are not part of the final coverage policy.

Five (5) commenters oppose assignment of facility certification and oversight to the Society for Cardiovascular Angiography and Interventions Carotid Accreditation Program (SCAI-CAP), while three (3) commenters support assigning certification and oversight to SCAI-CAP. Five (5) commenters suggest that a neutral body or one representing all specialties involved in CAS be responsible for facility certification and oversight. Three (3) commenters state that SCAI-CAP does not represent neurology, neurosurgery, or neuroradiology. One commenter states that SCAI-CAP appears to be a rigorous program, but is also interested in additional plans from other specialties. Two (2) commenters assert that CMS must discontinue its certification and recertification program in order for a separate entity to succeed.

Three (3) commenters support the development of a comprehensive formal certification and oversight process. One commenter asserts that stroke plans must be incorporated into facility requirements. Two (2) commenters contend that such a plan must be able to evaluate facilities and individual physicians separately.

Because CAS stakeholders have not reached a consensus regarding establishing a new comprehensive facility certification and oversight plan, CMS is not certifying any entity including SCAI-CAP at this time. The current CMS certification and recertification plan remains in effect. Additional discussion of our ability to certify another organization is presented in the analysis section of this document.

Physician Privileges

Several commenters raise specific concerns regarding physician privileges for CAS. One commenter states that only physicians trained or credentialed to treat acute stroke should perform CAS. One commenter asserts that facilities and physicians with poor morbidity and mortality rates should not be permitted to perform CAS.

CMS does not establish specific physician requirements for gaining and maintaining CAS privileges. Rather, this process is expected to be decided upon and established by facilities as part of their formal CAS programs. Facilities must have a means for granting physicians privileges and review performance in order to be approved by CMS to perform CAS procedures.

One commenter disagrees with training requirements discussed in the proposed decision memo; specifically those included in the external technology assessment (TA) which suggested that physicians be required to perform 50 CAS procedures per year to meet training requirements.

This information was utilized in CMS' evidence review for formulating the proposed decision memo. Referencing this information outside of the NCD language does not make it a requirement for coverage. As stated above, specific physician training requirements are to be determined by facilities as part the comprehensive CAS program facilities agree to have in place to be certified and recertified by CMS.

Carotid Endarterectomy (CEA)
Concerns and comments specific to CEA are included in public comments submitted regarding the proposed decision memo for CAS. Eight (8) commenters contend that if a surgeon must clear patients for CAS then CMS should develop a policy for CEA in which cardiologists and neurologists are required to clear patients for CEA. Two (2) commenters assert that Medicare should cover the same indications for both CEA and CAS in order to level the playing field. Two (2) commenters state that data is insufficient to cover both CEA and CAS for asymptomatic patients, and another commenter contends that outcomes for CEA are actually poorer than those reported in studies. Three (3) commenters request that CMS open a national coverage analysis and establish an NCD for CEA in asymptomatic patients.

Note. Issues raised regarding CEA cannot be resolved in this analysis. In order to address these, CMS would need to open a separate analysis and develop a separate policy specifically for Medicare coverage of CEA. Details for formulating and submitting a formal request are available at http://www.cms.hhs.gov/DeterminationProcess/02_howtorequestanNCD.asp.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (§ 1862(a)(1)(A)).

- **Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with symptomatic carotid artery stenosis $\geq$ 50%?**

In the prior decision, CMS provided coverage for patients who are at high risk for CEA surgery with symptomatic carotid artery stenosis ≥ 70% and patients with symptomatic carotid artery stenosis 50-70% in clinical trials or post-approval studies. Since then, 2 randomized clinical trials (EVA-3S, SPACE) and several reports based on registry data (Safian, CAPTURE, CASES-PMS) were published and provided evidence on this population. The SPACE and EVA-3S trials compared CAS to CEA in patients with symptomatic stenosis ≥ 50% and ≥ 60%, respectively, by NASCET criteria. However, they did not specifically limit inclusion to patients who were at high risk. Both SPACE and EVA-3S were stopped early and failed to show that CAS was not inferior to CEA. When considering these trials, a factor that may help explain why the results were different from the SAPPHIRE trial that provided much of the reasons for coverage is the use of distal embolic protection devices. In the SPACE trial, the majority of patients (416/567; 73%) were treated without using an embolic protection device. In the EVA-3S trial, the majority of patients (227/247; 92%) did receive a device but, for those patients who did not, there was a higher incidence of stroke or death at 30 days. While the use of distal embolic protection devices may help explain the outcomes, the results of these trials do not provide evidence to expand coverage of CAS to patients with symptomatic stenosis ≥ 50% and < 70%. The study reports by Chaer, Halabi and Park did not present results by symptom subgroups. The post-approval studies CAPTURE and CASES-PMS did not show significant differences overall between CAS and CEA, but both studies showed that symptomatic patients had higher 30-day adverse outcomes compared to asymptomatic patients.

SPACE and EVA-3S failed to show noninferiority of CAS compared to CEA (failed to show that CAS was not worse than CEA). Not only do these trials provide insufficient evidence for expansion of coverage, but they also raise questions about CAS for all patients with severe symptomatic carotid artery stenosis, particularly the results of EVA-3S which showed a 5.6% higher incidence of stroke and death. Since these studies did not present results by degree of stenosis, it is not possible to determine whether symptomatic patients with stenosis 50%-70% experienced better or worse outcomes than patients with stenosis ≥ 70%. EVA-3S did demonstrate that CEA could be performed with < 6% stroke and death rate for these patients.

The EVA-3S and SPACE trials did not limit inclusion to only patients at high risk for CEA surgery. It is unclear what, if any, influence this had on the outcomes, but it would be reasonable to believe that patients at low risk for CEA would have better outcomes than patients at high risk of adverse outcomes from surgery.

These trials do support the use of distal embolic protection devices and showed poor patient outcomes when they were not used. We required the use of distal embolic protection devices with CAS in our prior decision for the safety and protection of patients and will continue this requirement. If deployment of the distal embolic protection device is not technically possible, evidence suggests that the procedure should be aborted given the risks of CAS without distal embolic protection.

Since the posting of the proposed decision, the Blue Cross and Blue Shield Association TEC completed another review of CAS. The TEC concluded that CAS did not meet the TEC criteria to assess whether a technology improves health outcomes, the same conclusion reached in 2005. While the TEC reviewed essentially the same evidence, the TEC analyses compared CAS to the accepted rates of adverse outcomes established by the CEA trials and professional society statements. They noted "if CAS/EPD (embolic protection device) and CEA are equally safe and effective given similar patient characteristics, anesthetic approach, and can be performed with periprocedural stroke/death rates providing a net health benefit, then CAS is an alternative to CEA." The American Heart Association stated that: "For patients with recent TIA or ischemic stroke within the last 6 months and ipsilateral severe (70% to 99%) carotid artery stenosis, CEA by a surgeon with a perioperative morbidity and mortality of < 6% (Class I, Level of Evidence A) is recommended" (Sacco et al., 2006). Thus, for CAS to be considered an alternative to CEA and improve health outcomes, the perioperative morbidity and mortality should be < 6%.

The majority of commenters favored expansion of coverage to the 50-69% group stating that an expansion was appropriate because results from the CAPTURE, ARCHeR, CASES studies demonstrate the safety and effectiveness of CAS in this patient population. We evaluated these studies in our review and concluded that the more compelling evidence from the randomized trials (EVA-3S and SPACE) did not support expansion.

If the 6% perioperative morbidity (mainly stroke and MI) and mortality rate is required for a health benefit, then the evidence would suggest a noncoverage decision since the randomized trials had stroke and death rates higher than 6%. However, we believe that a noncoverage decision may limit access to carotid revascularization and will maintain the previous coverage for symptomatic patients at high risk for CEA with carotid artery stenosis $\geq$ 70%, since these patients are at higher risk from their disease compared with asymptomatic patients.

Thus the evidence based on the overall trial results is insufficient to support expanding coverage to symptomatic patients at high risk for CEA with stenosis 50%-70%, as we had suggested in the proposed decision. This patient population will remain covered in FDA-approved Category B IDE clinical trials and FDA-approved post approval studies as established in previous decisions.

- **Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with asymptomatic carotid artery stenosis $\geq$ 80%?**

For patients who are at high risk for CEA surgery with asymptomatic carotid artery stenosis $\geq$ 80%, several case series or registry reports and post-approval studies have been published since our prior decision which provided restricted coverage for these patients. The basis of our restricted coverage in the prior decision was the undocumented natural history of asymptomatic stenosis on medical therapy (lack of a medical control group in past studies), the lack of long term data on CAS in these patients, and the lack of data on CAS performed outside the controlled trial setting. While the outcomes of asymptomatic carotid artery stenosis with optimal medical therapy remain unclear and unstudied, the published reports provide evidence regarding our other prior concerns. The observational studies by Halabi, Chaer, Park and Safian provided supporting evidence for CAS in patients with asymptomatic stenosis $\geq$ 80%. The post-approval studies, CAPTURE and CASES-PMS, provided additional evidence on 30-day outcomes and some information on 1 year outcomes. The post-approval studies also showed that CAS outcomes were similar by provider volume (experience levels) and in settings outside clinical trials.

Since the posting of the proposed decision, the Blue Cross and Blue Shield Association TEC completed another review of CAS, as noted above, and again concluded that CAS did not meet the TEC criteria to assess whether a technology improves health outcomes. For asymptomatic carotid stenosis, the American Heart Association stated: "Prophylactic carotid endarterectomy is recommended in highly selected patients with high-grade asymptomatic carotid stenosis performed by surgeons with < 3% morbidity/mortality rates (Class I, Level of Evidence A)" (Goldstein et al., 2006). Thus, for CAS to be considered an alternative to CEA and improve health outcomes for asymptomatic patients with asymptomatic stenosis $\geq$ 80%, the perioperative morbidity and mortality rates should be less than 3%. No randomized trial or post approval study reviewed in this reconsideration showed that CAS can be performed at that level. This is particularly concerning for asymptomatic patients since these patients do not have symptoms by definition and may be exposed to risks from the procedure. As mentioned above, this situation highlights the need for a randomized trial comparing CAS with optimal medical therapy.

Public commenters were split on our proposed decision to expand coverage. Many individuals, particularly from the cardiology community, favored this change. Other specialties generally did not. The American College of Cardiology (ACC) and the Society for Cardiovascular Interventions and Angiography (SCAI) both recommended this change. The American Academy of Neurology (AAN), the American Association of Neurological Surgery (AANS) and Congress of Neurological Surgeons (CNS), the American Stroke Association (ASA), the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Neurovascular Coalition, the Society of Thoracic Surgeons (STS), and the Society for Vascular Surgery (SVS) did not support this change in their public comments.

In our proposed decision to remove the clinical study restriction for these asymptomatic patients, we failed to directly apply the accepted standards for revascularization, whether CEA or CAS, as recommended by the professional societies, to the study results. After reviewing the TEC assessment, we agree that the accepted standards for carotid revascularization should apply to CAS if it is to be considered an alternative to CEA. In reevaluating the study results, professional society evidence based guidelines and public comments, we now believe that our proposed decision to remove the added safety and patient protection components of clinical trials and post approved studies was premature. However, we also do not believe that a complete noncoverage decision at this point would be warranted because the results of the registry and post approval studies appear to trend towards improving outcomes from the early ARCHeR studies to CAPTURE and CASES (6.8%, 5.4%, 4.5%, respectively). As additional studies are conducted and experience is gained with the difficult techniques and importantly with appropriate patient selection, we anticipate that the perioperative morbidity and mortality rates will approach the recommended 3% level. Thus, CMS will continue to cover PTA and CAS in patients who are at high risk for CEA surgery and have asymptomatic carotid artery stenosis $\geq$ 80%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201) or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7).

- **Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery and $\geq$ 80 years of age?**

For patients who are ≥ 80 years of age, there is mounting evidence that the rate of death, stroke and MI after CAS is higher than for patients < 80 years. Stanziale and colleagues reported that octogenarians had a significantly higher rate of stroke, death or MI than nonoctogenarians (9.2% versus 3.4%, respectively; p=0.024). Safian and colleagues reported data that showed patients > 75 years had higher adverse outcomes than patients ≤ 75 (7.6% versus 4.8%). CAPTURE showed that patients ≥ 80 years of age had significantly higher rates of death, stroke or MI at 30 days than patients < 80 years (9.4% versus 5.3%, respectively; statistically significant, p-value <0.0001). SPACE found that patients > 75 years of age had a significantly higher rate of ipsilateral ischemic stroke and death at 30 days compared to patients ≥ 75 (11.01% versus 5.92%; exceeding the non-inferiority margin). Outcomes by age were not specifically reported by Chaer, Halabi, Mas, and Park.

The consistency of these findings across the trials and studies, observed in both symptomatic and asymptomatic patients, creates concerns for the safety of older patients undergoing CAS. This is also consistent with the recognition that patients ≥ 80 years of age are at higher risk for CEA. These patients were specifically excluded from the NASCET and ACAS trials. This was also one of the high risk criteria in the SAPPHIRE trial for carotid revascularization in general. The higher incidence of adverse outcomes is particularly concerning for patients who have asymptomatic stenosis. In many of these patients, more harm than good would have come from the PTA and CAS procedure. Thus, we will continue the coverage restriction for asymptomatic patients to trials and clinical studies, as noted above, including patients ≥ 80 years of age. We will not implement the proposed age restriction for symptomatic patients with carotid artery stenosis ≥ 70% since these patients have more limited treatment options and a higher incidence of adverse outcomes, as discussed above. This less restrictive view for symptomatic patients is also reflected in the AHA recommendations that set a higher acceptable rate of perioperative morbidity and mortality for symptomatic patients compared to asymptomatic patients (6% versus 3%, respectively). However, we will continue to monitor CAS study outcomes for these patients to determine if age restriction in the symptomatic population is warranted at a later date. We also strongly recommend that a careful review of the risks and benefits of any procedure, whether CAS or CEA, be done for all patients ≥ 80 years of age with input from the patients themselves to determine the most appropriate treatment, whether revascularization or medical therapy.

High Risk for CEA

Since our 2005 decision to expand CAS to subsets of patients that are at high risk for CEA, there have been various publications and discussions to attempt to clarify the determination of what qualifies a patient as at high risk CEA. Our 2005 decision, which provided basic information on high risk for CEA criteria, was modeled after the SAPPHIRE trial and past CEA trials that had addressed this issue. As discussed above, many commenters stressed the importance of establishing specific high risk criteria for CEA. CMS recognizes that there has been some difficulty in interpreting several of these high risk criteria for CEA. For example in the SAPPHIRE trial, "severe pulmonary disease" is not clearly defined. To help clarify, the recent American College of Cardiology Foundation Task Force consensus document provides useful information on high risk criteria for CEA to assist physicians and facilities in selecting appropriate patients for CAS (Table 7 reproduced from Bates et al., 2007):

Table 7. High-Risk Criteria for CEA

Anatomical Criteria	**Medical Comorbidities**
Lesion at C-2 or higher	Age ≥ 80 yrs
Lesion below clavicle	Class III/IV congestive heart failure
Prior radical neck surgery or radiation	Class III/IV angina pectoris
Contralateral carotid occlusion	Left main/ ≥2 vessel coronary disease
Prior ipsilateral CEA	Urgent (<30 days) heart surgery

Anatomical Criteria

Contralateral laryngeal nerve palsy
Tracheostoma

Medical Comorbidities

LV ejection fraction ≤30%
Recent (<30 days) myocardial infarction
Severe chronic lung disease
Severe renal disease

Distal embolic protection devices

We required the use of distal embolic protection devices with CAS in our prior decision for the safety and protection of patients and will continue this requirement. As evident from the public comment discussion, numerous commenters expressed disagreement with CMS' proposed clarification that embolic protection devices must be used for all CAS procedures. The EVA-3S trial provided direct evidence on the benefits of distal embolic protection devices ["the 30 day rate of stroke or death was significantly lower in patients treated with cerebral protection devices (7·9% vs 25% in those treated with stenting alone; p=0·03)" (Mas et al., 2007)]. As noted in comments (Naylor, 2006), the low rate of distal embolic protection device use in the SPACE trial may have contributed to adverse outcomes and the negative trial results. Kastrup and colleagues reported that the "use of cerebral protection devices significantly reduces the incidence of new DWI (diffusion-weighted imaging) lesions after CAS" (Kastrup et al., 2006). In addition, the ACCF/SCAI/SVMB/SIR/ASITN consensus document noted that "the use of EPDs appears to be important in reducing the risk of stroke during CAS" (Bates et al., 2007). Given the evidence and recommendation of these professional societies, we have decided to continue to require the use of a distal embolic protection device with PTA and stenting of the carotid artery. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection. Procedures that are continued without the use of an EPD are not eligible for Medicare coverage.

CAS in Stroke Patients

In the prior decision, CMS excluded coverage of CAS for patients with a modified Rankin score ≥ 3. This was based on the inclusion and exclusion criteria of the trials on CEA and CAS which we continue to believe is consistent with the available evidence. Carotid revascularization procedures including CEA and CAS should not be performed in patients who have had a prior disabling stroke. We are not using this scale as an outcome measure but solely as a patient selection factor.

In the Opinion of a Surgeon

The requestor also asked that CMS remove the language from the current NCD that requires patients eligible for CAS to be at high risk for CEA in the opinion of a surgeon. Various commenters have agreed with this position. In our 2005 opinion, we included this requirement based largely on the SAPPHIRE trial, which was the main evidence for expansion of coverage for CAS. In the SAPPHIRE trial, "each center was required to assemble a multidisciplinary team of physicians comprising a neurologist, either a vascular surgeon or a neurosurgeon, and an interventional physician" and "patients were randomly assigned to a procedure only if all members of the team were in agreement that the patient was a suitable candidate for either endarterectomy or stenting" (Yadav et al., 2004). As noted above in the high risk for CEA discussion, we believe that a surgeon qualified to perform CEA would be the most appropriate physician to determine whether a patient had an anatomical high risk criteria for CEA. CMS has determined with this final decision that requiring a surgeon credentialed to perform CEA to determine whether patients are at high risk for CEA was overly restrictive. We have removed this language from the final decision but would like to stress the importance of ensuring appropriate patient selection. As evident from the public comments discussed in the previous section, this issue has created a serious "turf" war between various physicians who treat carotid artery disease. Regardless of physicians' personal feelings for their colleagues, treatment decisions still must be made in the best interest of the patient. CMS encourages physicians of different specialties to work together to determine the best course of treatment for patients with carotid artery disease. Only by evaluating all possible treatment options can beneficiaries receive optimal care. We continue to strongly encourage consultation with a surgeon qualified to perform CEA and consideration of establishing a multidisciplinary team including a surgeon qualified to perform CEA to the evaluation of patients prior to performing carotid PTA and stenting as in the SAPPHIRE trial.

Facility Certification
In the prior decision, CMS determined that CAS with embolic protection is reasonable and necessary only if performed in facilities and by physicians who have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Given the evidence reviewed in this reconsideration, CMS continues to believe that facility certification is necessary. Since the implementation of the prior certification process, several organizations have included the CMS facility requirements into a broader review process. In addition, two evidence based guidelines have been released and discuss many of the same issues as noted in the evidence section.

Facilities approved by CMS to perform CAS procedures were approved for two (2) years after attesting that they met the minimum facility standards (listed above in Section II). CMS will continue these standards. However, we did not outline in the previous NCD any details on the data analysis or the process for recertification. We have provided that information to approved facilities separately but will define the process in this decision for greater clarity.

Data Analysis Details
CMS places significant importance on each facility's data analysis plan. We believe that this standard is crucial to ensuring the most optimal care for Medicare beneficiaries. The type of data collected needs to be sufficient to allow facilities to draw accurate conclusions. At a minimum, we believe the data elements should answer these questions:

What is the patient's date of birth?
When was the procedure performed?
Does the patient meet high surgical risk criteria (defined below)?

- Age $\geq$80;
- Recent (< 30 days) Myocardial Infarction (MI);
- Left Ventricle Ejection Fraction (LVEF) $\leq$ 30%;
- Contralateral carotid occlusion;
- New York Heart Association (NYHA) Class III or IV congestive heart failure;
- Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
- Renal failure: end stage renal disease on dialysis;
- Common Carotid Artery (CCA) lesion(s) below clavicle;
- Severe chronic lung disease;
- Previous neck radiation;
- High cervical Internal Carotid Artery (ICA) lesion(s);
- Restenosis of prior carotid endarterectomy (CEA);
- Tracheostomy;
- Contralateral laryngeal nerve palsy.

Is the patient symptomatic (defined below)?

- Carotid Transient Ischemic Attack (TIA): distinct focal neurologic dysfunction persisting less than 24 hours;
- Non-disabling stroke: Modified Rankin Scale < 3 with symptoms for 24 hours or more;
- Transient monocular blindness: amaurosis fugax.

What was the Modified Rankin Scale score if the patient experienced a stroke?
What was the % stenosis of the stented lesion(s) by angiography?
Was embolic protection used?
Were there any complications during hospitalization (defined below)?

- All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
- MI;
- All death.

With this NCD we are establishing that the data elements that answer these questions are necessary for standard five to be met. Most facilities will decide to collect many other data elements to answer additional questions. We encourage that, but do not require it.

This information must be collected on all patients undergoing CAS at each facility to ensure that the findings from each facility's data analysis are valid.

Facility certification and recertification
In the proposed decision memorandum, CMS presented the facility certification and oversight plan developed by the Society for Cardiovascular Angiography and Interventions (SCAI). We asked for public comments regarding this plan and the possibility of recognizing the facility certification and oversight role as meeting or exceeding our standards. As discussed in the public comment section of this document, significant concerns were raised by commenters about this possibility. Commenters, mostly professional specialty societies and manufacturers, were not comfortable with a specific specialty society taking over this role. Rather, they stated that facility certification and oversight should only be performed by a neutral third party or a multidisciplinary organization including representatives from all specialties involved in CAS.

While the SCAI-CAP plan is comprehensive and rigorous, CMS believes additional input from other specialty societies would be helpful. As with all issues surrounding CAS, this will require stakeholders to cooperate and work closely together to meet the same end goal. We know that most CAS stakeholders wish to see a more comprehensive plan for facility certification and oversight than the plan CMS currently has in place; however, in order to best serve patients and equally involve all stakeholders, the stakeholders themselves must work together to develop a mutually agreed upon plan. The CMS certification plan will continue until a comprehensive, mutually agreed upon plan is developed, tested, presented to CMS and endorsed through an NCD.

The 2005 NCD found CAS to be reasonable and necessary under certain circumstances including when performed in CMS approved facilities. Facilities are required to meet the five standards described in the Section B4 of the current NCD (20.7). We require facilities to submit verification to us that the first four standards had been met and the process they would use to meet the fifth standard—data analysis. As an alternative, facilities that were approved as trial sites for many of the ongoing clinical trials were considered to have met these standards. Until such time as we authorize another entity to certify facilities, we will continue that process.

The current NCD notified approved facilities that the certification was only valid for two years. Over the last several months, we have worked with the approved facilities and various specialty societies to develop a recertification process. We have held several public meetings to assist in this process. We are formally outlining that process here.

For recertification purposes, facilities must attest to continuing to meet the original facility standards. We will require facilities to provide written documentation that the first four standards have been met. Because of the significant importance that we place on the facility's data analysis plan, we are requiring that each facility submit to us the data elements outlined above along with the Medicare identification number for Medicare beneficiaries. We will review this data to ensure that the data elements that we require are being collected for all patients and that all Medicare beneficiaries for whom we have paid claims are included in the data analysis.

To assist facilities in the recertification process, we are establishing the following process:

At 23 months after initial certification:

- Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed in the Medicare NCD Manual, 20.7.

At 27 months after initial certification:

- Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.
- Data elements:

Patients' Medicare identification number if a Medicare beneficiary;
Patients' date of birth;
Date of procedure;
Does the patient meet high surgical risk criteria (defined below)?

- Age $\geq$80;
- Recent (< 30 days) Myocardial Infarction (MI);
- Left Ventricle Ejection Fraction (LVEF) $\leq$ 30%;
- Contralateral carotid occlusion;
- New York Heart Association (NYHA) Class III or IV congestive heart failure;
- Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
- Renal failure: end stage renal disease on dialysis;

- Common Carotid Artery (CCA) lesion(s) below clavicle;
- Severe chronic lung disease;
- Previous neck radiation;
- High cervical Internal Carotid Artery (ICA) lesion(s);
- Restenosis of prior carotid endarterectomy (CEA);
- Tracheostomy;
- Contralateral laryngeal nerve palsy.

Is the patient symptomatic (defined below)?

- Carotid Transient Ischemic Attack (TIA): distinct focal neurologic dysfunction persisting less than 24 hours;
- Non-disabling stroke: Modified Rankin Scale < 3 with symptoms for 24 hours or more;
- Transient monocular blindness: amaurosis fugax.

Modified Rankin Scale score if the patient experienced a stroke;
% stenosis of stented lesion(s) by angiography;
Was embolic protection used?
Were there any complications during hospitalization (defined below)?

- All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
- MI;
- All death.

Recertification is effective for two (2) additional years during which facilities will be required to submit the data elements every April 1 and October 1.

CMS will consider the approval of national carotid artery stenting registries that provide CMS with a comprehensive overview of the registry and its capabilities, and the manner in which the registry meets CMS data collection and evaluation requirements. Specific standards for CMS approval are listed below. Facilities enrolled in a CMS approved national carotid artery stenting registry will automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the registry to submit required data to CMS for the hospital. A list of approved registries will be available on the CMS coverage website.

National Registries

As noted above, CMS will approve national registries developed by professional societies and other organizations and allow these entities to collect and submit data to CMS on behalf of participating facilities to meet facility certification and recertification requirements. To be eligible to perform these functions and become a CMS approved registry, the national registry, at a minimum, must be able to:

1. Enroll facilities in every US state and territory;
2. Assure data confidentiality and compliance with HIPAA;

3. Collect the required CMS data elements as listed in the above section;
4. Assure data quality and data completeness;
5. Address deficiencies in the facility data collection, quality and submission;
6. Validate the data submitted by facilities as needed;
7. Track long term outcomes such as stroke and death;
8. Conduct data analyses and produce facility specific data reports and summaries;
9. Submit data to CMS on behalf of the individual facilities;
10. Provide quarterly reports to CMS on facilities that do not meet or no longer meet the CMS facility certification and recertification requirements pertaining to data collection and analysis.

Registries wishing to receive this designation from CMS must submit evidence that they meet or exceed our standards. Though the registry requirements pertain to CAS, CMS strongly encourages all national registries to establish a similar mechanism to collect comparable data on CEA. Having both CAS and CEA data will help answer questions about carotid revascularization, in general, in the Medicare population.

IX. Decision

Summary of Changes
With the exception of clarifications regarding the use of embolic protection devices and the facility certification and recertification process, we have elected not to implement the changes in covered indications for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting that were outlined in the proposed decision memorandum. Therefore, coverage for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting remains as follows:

1. Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq$ 70%. Coverage is limited to procedures performed using FDA approved carotid artery stenting systems and embolic protection devices;

2. Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7);

3. Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq$80%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7).

CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible.

The five facility certification requirements are also unchanged. We modify the process for completing facility certification and recertification in the NCD Manual. This modification includes specific data submission requirements for facility recertification as well as a timeline for this process.

CAS for patients who are not at high risk for CEA remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.

This decision only changes coverage criteria in section B4 of the Medicare NCD Manual for CAS (20.7). Coverage as determined in the other sections of 20.7 will continue without modification.

The NCD language can be found in Appendix B of this decision memorandum.

Table 1. Carotid Artery Stenting

Author/ Year	VII. Study Design, Patient Characteristics	Demographics	Results
Chaer et al., 2006	Observational study / Registry analysis CEA vs CAS; N=693 (545 and 148, respectively). Primary outcome = death, stroke, MI within 30 days or death or ipsilateral stroke for duration of follow-up. All patients were at high risk for CEA. No other inclusion or exclusion criteria were specified.	Mean age = 73 yrs.	Primary outcome = 4.0% CEA; 3.4% CAS.
Cordis, 2006 CASES-PMS	Observational study / Registry analysis CAS; N = 1479. Primary outcome = all stroke, death, MI within 30 days. Symptomatic patients $\geq$50% stenosis by ultrasonography or angiography (n=322; 21.8%); Asymptomatic $\geq$80% stenosis (n=1157; 78.2%).	Mean age = 73 yrs.	Primary outcome = 4.8%. Symptomatic patients = 5.9%. Asymptomatic patients = 4.5%.

Author/ Year	VII. Study Design, Patient Characteristics	Demographics	Results
	All patients were at high risk for surgery.		
Halabi et al., 2006	Case series CAS; N = 116. Primary outcome = in-hospital death, stroke and MI. All patients were at high risk for CEA. Symptomatic patients ≥60% stenosis by angiography; Asymptomatic ≥70% stenosis by angiography.	Mean age = 71 yrs.	Primary outcome = 2.6% CAS.
Gray et al., 2006 ARCHeR	3 case series; N =581. Primary outcome = all stroke, death, MI within 30 days. Symptomatic patients ≥50% stenosis by angiography (n=138; 23.8%); Asymptomatic ≥80% stenosis by angiography (n=443; 76.2%). All patients were at high risk for surgery.	Mean age = 70 yrs. Age≥80 =15.5%.	All stroke, death and MI = 8.3% (48/581). Symptomatic patients = 13.0% (18/138). Asymptomatic patients = 6.8% (30/443).
Gray et al., 2006 CAPTURE	Observational study / Registry analysis CAS; N = 3500. Primary outcome = all stroke, death, MI within 30 days. Symptomatic patients ≥50% stenosis by angiography (n=482; 13.8%); Asymptomatic ≥80% stenosis by angiography (n=3018; 86.2%). All patients were at high risk for surgery.	Mean age = 73 yrs. Age≥80 =23.7%.	All stroke, death and MI = 16.9% (40/581). Symptomatic patients = 13.0% (18/138). Asymptomatic patients = 5.4% (24/443). Age≥80 = 9.4%; Age<80 = 4.8%.
Mas et al., 2006 EVA-3S	Randomized noninferiority trial CEA vs CAS; N=520 (259 and 261, respectively). Primary outcome = any stroke or death within 30 days. All symptomatic patients with stenosis ≥60% by NASCET criteria. Symptoms were hemispheric or retinal transient ischemic attack or nondisabling stroke or retinal infarct within 120 days. There was no inclusion criteria based on surgical risk. Patients with modified Rankin ≥3 were excluded.	Mean age = 70 yrs. Age≥75 =36.3%.	Any stroke or death = 3.9% CEA; 9.6% CAS (relative risk = 2.5; 95%CI 1.2-5.1). Trial was stopped early for safety and futility.
Park et al., 2006	Observational study / Database analysis CEA vs CAS; N=94 (48 and 46, respectively). Outcomes included death, stroke, length of stay, costs. Symptomatic patients ≥50% stenosis by duplex ultrasonography; Asymptomatic ≥80% stenosis. There was no inclusion criteria based on surgical risk.	Mean age = 71 yrs.	Perioperative mortality = 2% CEA; 0% CAS. Stroke = 4% CEA; 2% CAS.
Safian et al., 2006 CREATE	Multicenter registry analysis CAS; N=419. Primary outcome = all death, ipsilateral stroke, procedure-related contralateral stroke, MI within 30 days. Symptomatic patients ≥50% stenosis by NASCET criteria (n=73; 17.4%); Asymptomatic ≥80% stenosis (n=346; 82.6%). Symptoms were hemispheric TIA or stroke within 6 months. All patients were at high risk for surgery.	Mean age= 74 yrs. Age >75 yrs =50%.	All death, ipsilateral stroke, procedure-related contralateral stroke, MI = 6.2% (26/419). Symptomatic patients MACCE = 16.4% (12/73). Asymptomatic patients MACCE = 4.0% (14/346). Age >75 = 7.6%; Age≤75 = 4.8%.
SPACE Group, 2006	Randomized noninferiority trial CEA vs CAS; N=1183 (595 and 605, respectively). Primary outcome = ipsilateral ischemic stroke or death within 30 days.	Mean age= 68 yrs. Age > 75 = 21.6%.	All ipsilateral stroke or death = 6.3% CEA vs 6.8% CAS. Trial was stopped early.

Author/ Year	VII. Study Design, Patient Characteristics	Demographics	Results
	Symptomatic patients ≥50% stenosis by NASCET criteria. Symptoms were amaurosis, TIA or stroke. No inclusion criteria based on surgical risk. Patients with Modified Rankin > 3 were excluded.		CAS Age >75 = 11.0% (12/109); CAS Age≤75 = 5.9% (29/490).
Stanziale et al., 2006	Observational study / Database analysis CAS; Age ≥80 vs Age <80; N=360 (87 and 295, respectively). Primary outcome = stroke, death, MI within 30 days. Symptomatic patients ≥50% stenosis by NASCET criteria; Asymptomatic ≥80% stenosis.	Mean age = 69 and 83, respectively.	Primary outcome = 9.2% and 3.4%, respectively (p=0.02).

Appendices [PDF, 183KB]

[1] Evidence supporting our earlier policies is summarized in our earlier decision memoranda dated July 1, 2001, October 12, 2004, and March 17, 2005. This evidence is included in the record of our previous national coverage determinations. For the sake of brevity, we will not summarize all of the evidence supporting the policies that are being retained. Instead, we will incorporate the records of the earlier NCDs into the record of this NCD.

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